JUN - 1 2012

510(k) Summary K121345

Halifax Biomedical Inc.
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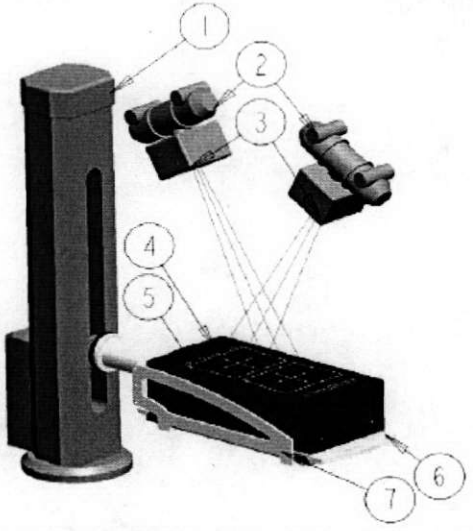
Contact: Chad Munro, CEO President
Date Prepared: June 1, 2012

1. Identification of the Device:
   Proprietary-Trade Name: SR Suite 1.0
   Classification Name: Stationary X-ray system,
   Product Codes Product Codes KPR, MQB, and LLZ
   Common/Usual Name: Diagnostic X-ray Units with Digital X-ray receptor panel.

2. Equivalent legally marketed devices: The SR Suite 1.0 employs the same digital panel as described in K092439, the Canon CXDI-50RF and many of the same components described in K090279, the Sedecal Millennium Plus. The SR Suite employs the software cleared in K042383, the RSA-CMS.

3. Indications for Use (intended use): This is a stationary digital x-ray system for general radiography and RSA (Roentgen Stereophotogrammetric Analysis procedures). Not for mammography.

4. Description of the Device: The Halifax SR Suite is compromised of two regulatory approved X-Ray imaging systems; the two systems are integrated through a synchronization switch. The switch allows the two X-Ray imaging systems to fire simultaneously, providing a pair of X-Ray images from different perspectives to be taken at the exact same time. This process allows for Roentgen Stereophotogrammetric Analysis (RSA). RSA is a stereo x-ray technique that enables measurements more precise than single plane radiography based on phantom precision studies. The resulting level of precision provides measurements of joint replacement stability. The components are: 1: Stand, 2: Tube housings, 3: Collimators, 4: Reference Box Cover, 5: SR reference box, 6: Detector Plates, 7: SR Support Arm. The SR Suite employs the software cleared in K042383, the RSA-CMS.



5. The key difference between the Halifax SR Suite 1.0 and the predicate Sedecal Millennium is the use of two generators, tube heads, collimators, and detector panels in order to be able to take simultaneous images from two angles as shown in the illustration above. This allows for the application of the RSA-CMS software cleared in K042383. The SR Suite employs the RSA-CMS software cleared in K042383.

This software was designed specifically to perform Roentgen Stereophotogrammetric Analysis.

6. Testing summary: External laboratory safety and EMC testing was performed to standards IEC 60601 + Am1& 2 and IEC 60601-1-2. Internal laboratory testing was performed to determine Effective Doses for RSA Examinations and RSA precision, including bench testing that was performed using phantoms to evaluate variables in the image acquisition (e.g., scatter, setup, marker size) that could impact the system performance. The precision was evaluated using a stationary carbon fiber phantom box and a rotating carbon fiber plate. Translational precision was evaluated by taking 10 repeated measures of the carbon fiber phantom box containing two grids of 26 tantalum beads, and by calculating the standard deviation of the repeated measurements of the inter-bead distance. Translational precision was found to be x = 0.0018mm, y = 0.0017mm, and z =0.0039 mm. In the same manner, a combined precision was calculated using a rotating carbon fiber plate containing 47 tantalum beads. The combined precision was found to be 0.005mm. Software validation and risk analysis was performed. Clinical images were obtained to validate total system performance.

7. Safety and Effectiveness, comparison to predicate device. The results of bench, clinical, and standards testing indicates that the new device is as safe and effective as the predicate devices. Risk analysis has been performed.

8. Substantial Equivalence Chart, Halifax SR Suite 1.0

Characteristic	**Sedecal Millennium Digital K090279**	**Halifax SR Suite 1.0**
Intended Use:	These Digital Radiographic Systems are intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.	This is a stationary digital x-ray system for general radiography and RSA (Roentgen Stereophotogrammetric Analysis procedures.) Not for mammography.
Generator	Sedecal SHF635RF	Sedecal SHF635RF (Two used)
Maximum output	50 kW to 80 kW.	64 kW (Two used)
Stand	Supplied by Sedecal	Sedecal and Acceleray
Image Acquisition	Digital or Film	Digital, dual panels.
Digital Panel Size	17 x 17	17 x 17
Digital Panel Supplier	Canon panels, multiple models: 50C, 50G, 40C & 40G	Canon CXDI-50RF (Two used, cleared in K092429)
Digital Resolution	Pixel size160 × 160 µm Image matrix size 2208 × 2688 pixels Number of pixels Approx. 5.9 million pixels	Pixel size 160 × 160 µm Image matrix size 2208 × 2688 pixels Number of pixels Approx. 5.9 million pixels
Software	DICOM, via O&R software cleared in K091364	The SR Suite employs the software cleared in K042383, the RSA-CMS. The software was designed specifically to perform Roentgen Stereophotogrammetric Analysis.
Acquisition Software	The Sedecal Millenium employs the acquisition softare cleared in the Canon digital panels: K023750, K031337, and K060433,	SR Suite 1.0 employs the acquisition software cleared in K092429 for the digital panel.
Collimator	Ralco or Heustis	Ralco R225
Safety	UL listed	UL listed

9. Conclusion: After analyzing bench, clinical, risk analysis, and standards testing data; it is the conclusion of Halifax Biomedical that the SR Suite 1.0 X-Ray System is as safe and effective as the predicate devices, has no significant technological differences, and has no new indications for use, (In fact USING the predicate devices) thus rendering it substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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JUN - 1 2012

Re: K121345
Trade/Device Name: SR SUITE 1.0
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR, LLZ, and MQB
Dated: May 2, 2012
Received: May 4, 2012

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):K121345

Device Name: SR SUITE 1.0

Indications For Use:

This is a stationary digital x-ray system for general radiography and RSA (Roentgen Stereophotogrammetric Analysis procedures.) Not for mammography.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K121345